DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

May 1, 2015

Den-Mat Holdings, LLC
Ms. Helen Ragus
Regulatory Specialist
1017 W. Central Avenue
Santa Maria, CA 93436

Re: K143679
Trade/Device Name: nuance® FLOW
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: March 31, 2015
Received: April 1, 2015

Dear Ms. Ragus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name

nuance® FLOW

Indications for Use *(Describe)*

nuance® FLOW is recommended for the following types of applications:
1) Direct restorations of anterior or posterior teeth
2) Cavity base/liner
3) Intraoral repairs of fracture crowns/bridges

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DenMaf

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K143679

510(k) SUMMARY

Submitter:

Owner's Name:	Den-Mat Holdings, LLC
Address:	1017 W. Central Avenue Lompoc, CA 93436 U.S.A.
Phone Number:	805 346 3700
Fax Number:	805 347 7940
Contact Person:	Helen Ragus Regulatory Specialist 805 346 3700, X2932 hragus@denmat.com
Date of Summary Preparation:	April 30, 2015

Device Name:

Trade Name:	nuance® FLOW
Common Name:	Light-Curable Dental Restorative Material
Classification Name:	Material, Tooth Shade Resin
Classification Number:	Class II (21 CFR 872.3690)
Product Code	EBF

Predicate Device:

S&C Polymer GmbH	K990108

Description of the Device

nuance® FLOW is a Class II medical device intended to be used as a composite tooth restorative. According to the applicable FDA recognized consensus standard, ISO 4049- "Dentistry- Polymer-based restorative materials", this device is classified as Class 2: materials whose setting is affected by the application of energy from an external source, such as blue light or heat (Group 2). nuance® FLOW is DenMat's Flowable for use in direct restorations of anterior or posterior teeth. They are polymerizable dental monomer resins that are chemically-cured when exposed to dental curing lights. It is used to form a durable, esthetic restoration. It is a lower viscosity material that allows it to be used when ease of application and thinner layers are needed. nuance® Flow may be appropriate for dental Class I, III, IV and V type restorations where maximum mechanical strength and wear resistance is not required. A small amount of fluoride (.5-.7%) is included to minimize likelihood of secondary caries. nuance® FLOW is packaged in a 1 mL single• barrel syringe and offered in 8 shades: A1, A2, A3, A3.5, B1, B2, BL1 and BL2.

Intended Use of the Device

nuance® FLOW is intended to be used as a composite tooth restorative.

Indications for Use of the Device

nuance® FLOW is recommended for the following types of applications:

1) Direct restorations of anterior or posterior teeth
2) Cavity base/liner
3) Intraoral repairs of fracture crowns/bridges

Substantial Equivalence Discussion

1) Intended Uses/Indications for Use

nuance® FLOW and the predicate device LC FLOWFILL are both intended to be used as a composite tooth restorative.

nuance® FLOW and the predicate device LC FLOWFILL are recommended for the following types of applications: direct restorations of anterior or posterior teeth, in cavity liner/base and intra-oral repairs of fractured crowns and bridges.

Scientific literature have been evaluated to determine the equivalence of similar products used for the same indications. The intended uses and indications for use of the subject device are substantially equivalent to that of the predicate device.

2) Chemical Components

Chemical components in nuance® FLOW are used in the predicate device. Scientific literature have been evaluated to support the use of similar products for the same indications. The predicate device has not been a focus of any advisory notice or recalls, according to the post-market adverse event reporting requirements in the United States. The conclusion can be made that the chemical composition of the subject device is substantially equivalent to that of the predicate device.

3) Technological Characteristics and Performance

nuance® FLOW and the predicate device LC FLOWFILL were both tested according to the applicable FDA recognized standard ISO 4049 Dental--- polymer based restorative materials. This standard specifies requirements for dental polymer-based restorative materials supplied in a form suitable for mechanical mixing, hand-mixing, or intra-oral and extra-oral external energy activation, and intended for use primarily for the direct or indirect restoration of cavities in the teeth and for luting. Testing results indicate that nuance® FLOW was as effective and performs as good as the predicate device. In addition, scientific literature was evaluated to support the use of similar products for the same indications. The conclusion can be made that the technological characteristics and performance of the subject device are substantially equivalent to that of the predicate device.

Biocompatibility

The subject device is categorized as an external communicating device with contact to tissue/bone/dentin and is a permanent contact device. nuance® FLOW's chemical composition as well as materials and technological properties is substantially equivalent to that of the predicate device. Both devices are made of materials with a long history of safe use. Biocompatibility of the predicate device was established according to EN 30993 and ISO 10993 Biological evaluation of medical devices. Cytotoxicity study resulted in no signs of cytotoxicity observed. Examination of irritation revealed no intracutaneous reactivity. The predicate device has not been a focus of any advisory notice or recalls according to the post-market adverse event reporting requirements in the United States. Available studies from scientific literatures support the biocompatibility of nuance® FLOW. No biocompatibility test is required to establish substantial equivalence.

Comparative Performance Data

IS0-4049 Dental--- polymer-based restorative materials: Test Results			
	Requirement	**nuance[181] FLOW**	**LC FLOWFIL**
Film thickness	<50 micron	37.8 micron	40.5 micron
Sensitivity to ambient light	>60 seconds, no cure	pass	Pass
Depth of cure	>0.5mm	2.49	2.55
Flexural strength	>50Mpa	85.9 Mpa	79.0Mpa
Water sorption/solubility	≤40 micrograms/mm3	27.2	25.9
Shade/color stability	match standard	match/pass	match/pass
Radio opacity	≥1.0mm mm aluminum	3mm	2mm

Summary of Features and Characteristics of the Device Compared to the Predicate Device:

Product	510(k)	Dental Applications*	Chemical Composition	Material Properties
nuance® Flow	K143679	- direct restorations of anterior or posterior teeth - in cavity liner/base - intra-oral repairs of fractured crowns and bridges	-Light-cure -Methacrylate resin based -Contains fluoride	-excellent color stability - resistance to abrasion -high strength -high gloss polishability -radiopaque
LC FLOWFILL	K990108	- tooth fillings - sealings -cementing (Current terminology used for the submission application)	-Light-cure -Methacrylate resin based -Contains fluoride	-excellent color stability - resistance to abrasion -high strength -high gloss polishability - radiopaque

* - All listed Dental Applications are commonly used dental restorative material applications.

Conclusion

The information provided in this 51O(k) submission demonstrates that nuance® FLOW is substantially equivalent to the predicate device LC FLOWFILL in terms of intended use, indications for use, chemical composition and physical properties.

It is concluded that the information supplied in this submission has proven the substantial equivalence of this product.